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EXAMINER
EPPS -SMITH, JANET L

ART UNIT	PAPER NUMBER
1633	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/598,597	DAVIES ET AL.	
	Examiner	Art Unit	
	Janet L. Epps-Smith	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 November 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-9 and new claims 10-16 are pending for examination.

Claim Objections

2. The objection to claim 8 as set forth in the prior Office Action is withdrawn in response to Applicant's amendment to the claim.

Response to Arguments

Claim Rejections - 35 USC § 102

3. Claims 1-3, and 8-16 remain rejected under 35 U.S.C. 102(b) as being anticipated by Baksh et al. (WO02/086104A1; ¶ numbers cited below are taken from the US patent application 20040137612).

4. Applicant's arguments filed 11/10/2009 have been fully considered but they are not persuasive. Applicants traverse the instant rejection on the grounds that Baksh et al. only describe the use of non-static suspension culturing in serum to expand progenitor cell numbers, and then differentiating the expanded progenitors by plating in defined media. Contrary to Applicant's assertions Baksh et al. teach the following at ¶ [0079] "[F]or differentiation into chondroblasts, the progenitors can be grown in serum-free DMEM supplemented with TGF-.beta. in suspension culture, for about 14 days or more." This passage clearly teaches the use of non-static conditions in a serum-free culture of progenitor cells, and therefore reads on claims 1-3, and 8-11. As stated in the prior Office Action, Baksh et al. teach that [0063] "[T]he invention relates to human progenitor cells from which a variety of non-hematopoietic cell types can differentiate. Because of the variety of non-hematopoietic cells that can differentiate from the present

progenitor cell population, it is referred to herein as a population of non-hematopoietic progenitor a cells. Such a population comprises mesenchymal progenitor cells (MPCs), as well as other non-hematopoietic progenitor cells. Such progenitor cells may also be referred to as "precursor" cells, and these terms are considered equivalent herein for the reason that both progenitors and precursors are able to give rise to differentiated cell type. [0064] The present progenitor cell population results from the non-static suspension culturing of cells of the type obtained from bone marrow, using techniques that are described in greater detail in the examples herein. It is to be appreciated that her comparable and known sources of such progenitor cells can also be used, as noted hereinabove, including particularly umbilical cord and placental blood, peripheral blood, skin, adipose, and muscle. This aspect of Baksh et al. reads on claims 15-16.

5. The methods of Baksh et al. comprise wherein the input population of cells comprise CD45- and CD45+ cells, the descriptions for Figures 6 and 7 of page 9.

In a preferred embodiment, Baksh et al. disclose the following: “1. An enriched progenitor cell population comprising non-hematopoietic progenitor cells extractable from bone marrow, wherein the cell population is substantially devoid of at least one type of hematopoietic progenitor cell. 2. An enriched progenitor cell population according to claim 1, characterized by the absence of at least one hematopoietic progenitor cell type, wherein said cell type is one having a surface marker selected from CD3, CD14, CD39, CD45, CD66, CD119. “ (See claims of publication). Absent evidence to the contrary, although the expansion conditions of Baksh et al. comprise the

use of serum, the isolated cell populations produced by these methods would have the same characteristics as the isolated population of cells recited in instant claims 9-10.

Baksh et a. teach pharmaceutical formulations of the disclosed progenitor cells, see ¶[0084], which recites: "[F]or the purposes described herein, either autologous or allogeneic progenitors of the present invention can be administered to a patient either in differentiated or undifferentiated state, genetically altered or unaltered state, by direct injection to a tissue site, systemically, with an acceptable matrix, or in combination with a pharmaceutically acceptable carrier. " Thus Baksh et al. reads on claims 13-14.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

7. Claims 1-2, 7-8, 11, and 13-15 are rejected under 35 U.S.C. 102(a) as being anticipated by Kallos et al. (2003).

8. Kallos et al. teach a method for the large scale culturing of neural stem cells (NSCs) by non-static, non-adherent suspension in serum-deprived nutrient medium. Kallos teaches the expansion of human and murine NSCs on a large scale in suspension bioreactors in a new serum-free media. (See abstract) Absent evidence to the contrary, the NSCs suspension disclosed in this reference would read on a pharmaceutical formulation.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baksh et al. WO 2002/086104 in view of Cancedda et al. (US .

11. Baksh et al. teach the following specific embodiments, see pages 26-28 of this reference:

A. An enriched progenitor cell population comprising non-hematopoietic progenitor cells extractable from bone marrow, wherein the cell population is substantially devoid of at least one type of hematopoietic progenitor cell.

B. An enriched progenitor cell population according to embodiment 1, characterized by the absence of at least one hematopoietic progenitor cell type, wherein said cell type is one having a surface marker selected from CD3, CD14, CD39, CD45, CD66, CD119.

C. A method for expanding human non-hematopoietic progenitor cells, the method comprising the step of subjecting a progenitor cell population comprising non-hematopoietic progenitor cells to non-static suspension culturing in a suitable medium for a period of time effective to expand said progenitor cells.

D. The method according to embodiment 5 wherein said progenitor cell population comprises human mesenchymal progenitor cells.

E. The method according to any one of embodiments A-D, wherein said growth medium includes growth factors for human mesenchymal progenitor cells.

F. The method according to embodiment E wherein said growth factors are cytokines.

G. The method according to embodiment F wherein said cytokines are a mixture of stem cell factor and interleukin-3.

H. An expanded progenitor cell population, prepared by the suspension culturing of an enriched progenitor cell population according to any one of embodiments A-D.

I. A composition, useful for delivering non-hematopoietic progenitor cells to an environment conducive to the formation of differentiated cells therefrom, the composition comprising an expanded population of human progenitor cells according to any one of embodiments A-D, G or H, and a vehicle for delivering said cells to said environment.

J. A progenitor cell population as set forth in any one of the above embodiments, in combination with one or more factors for inducing the differentiation thereof.

K. A cell population representing a new compartment of progenitor cells, said cell population comprising progenitor cells which, under differentiation conditions give rise to a variety of non-hematopoietic cell types including osteoblasts, adipocytes and myoblasts, wherein said cell population results from the non-static suspension culturing of an input population of progenitor cells obtained without prior selection based on cell adherence.

12. Baksh et al. does not teach the use of a serum-free medium for the expansion of mesenchymal cells. However, the methods of Baksh et al. recite wherein a suitable medium for culturing non-hematopoietic cells types, including mesenchymal progenitor cells is used.

13. Cancedda et al. teach methods comprising the use of serum free media for the growth and proliferation of mesenchymal stem cells in culture. See the following embodiments of Cancedda et al. set forth on page 3 of this reference:

8. A method for culturing mesenchymal stem cells, which comprises growing said cells in a serum-free composition comprising FGF-2, LIF, SCF, pantotenate, biotin and selenium.

9. The method according to claim 8, wherein the serum-free composition further comprises EGF, PDGFbb, IGF-1, ascorbic acid, cholesterol, albumin, β-mercaptoethanol, dexamethasone and transferrin.

10. The method according to claim 8, wherein the serum-free composition further comprises a minimum essential medium.

11. The method according to claim 9, wherein the serum-free composition further comprises a minimum essential medium.

12. A serum-free culture medium for mesenchymal stem cells comprising FGF-2, LIF, SCF, pantotenate, biotin and selenium.

13. The serum-free culture medium according to claim 12, further comprising EGF, PDGFbb, IGF-1, ascorbic acid, cholesterol, albumin, β-mercaptoethanol, dexamethasone and transferrin.

14. The serum-free culture medium according to claim 12 further comprising a minimum essential medium.

15. The serum-free culture medium according to claim 12 further comprising a minimum essential medium.

It would have been obvious to the ordinary skilled artisan to modify the teachings of Baksh et al. with the teachings of Cancedda et al. in the design of the instant invention. One of ordinary skill in the art would have been motivated to make this modification since Baksh et al. clearly teach that the disclosed methods of culturing should be performed in the presence a medium that was suitable for culturing non-hematopoietic progenitor cells, including mesenchymal progenitor cells, and Cancedda et al. disclose a medium suitable for culturing of mesenchymal stem cells. See MPEP § 2144.06 [R-6], which teaches that it is *prima facie* obvious for the ordinary skilled artisan to substitute art recognized equivalents known for use in the same purpose.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Smith whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Epps-Smith/
Primary Examiner, Art Unit 1633